REMARKS

Claims 1-8 are pending in this application. Clamis 2, 5 and 9-17 have been cancelled. Claims 1 and 8 have been amended. No new claims have been added.

Claims 1-8 have been rejected under 35 U.S.C. §§ 102(b) as being anticipated by Grawe, et al. (US Pat. No. 6,902,741). Grawe relates to transdermal laminated products comprising an adhesive matrix which contains inclusions of a sex hormone in a hydrophilic non-crosslinked polymer. The instant claims have been amended to recite an oral steroid hormone product comprising at least one steroid hormone in admixture with lactose, wherein the lactose stabilizes the steroid hormone in its non-crystalline. Grawe nowhere teaches such a product. Since Grawe fails to teach each and every aspect of the claims as amended, this reference does not provide the proper basis for an anticipation rejection. Accordingly, applicants request that the rejection based on Grawe be withdrawn.

Claims 1-8 have been rejected under 35 U.S.C. §§ 102(b) and 103(a) over Gast '405. The Examiner notes that the instant claims differ from Gast in that the claims recite non-crystalline steroid hormone. The Examiner argues that the claimed invention would be obvious since no unexpected results and/or criticality of the non-crystalline hormone is shown. Applicants submit that the rejections issued under sections 102 and 103 are not well-taken and should be withdrawn.

As the Examiner acknowledges in the Office Action, the claims differ from Gast in that the instant claims recite non-crystalline steroid hormone, and Gast teaches a crystalline form. Since the reference does not teach each and every element of the claimed invention, rejection of the claims as being anticipated by Gast is improper. Accordingly, applicants request that the rejection under 102(b) be withdrawn.

As to the 103(a) rejection over Gast in view of Merck, applicants submit that the criticality of the steroid hormone in non-crystalline form is clearly set forth in the specification. Applicants direct the Examiner to page 6, lines 15-23 of the specification wherein it is noted that steroid hormones can exist in various solid state forms and that the particular solid state form may significantly affect properties such as dissolution rate and physical/chemical stability. It is further noted in that section of the specification that the higher energy, non-crystalline solid state form will exhibit an increase in dissolution rate over the more stable, lower energy crystalline form. At page 7, line 30 to page 8, line 2,

applicants point out that in the manufacture of steroid hormone products it would be highly desirable to increase the dissolution rate of the hormone while at the same time either improving or at least not reducing the physical/chemical stability of the hormone.

These objectives are achieved by the claimed invention, as shown by the data set forth in Tables 1-4. In particular, the data in Table 1 demonstrate the difference in dissolution rates for non-crystalline norgestimate as compared to the lower-energy crystalline form. Note that the dissolution rate for amorphous norgestimate at 60 minutes is about the same as the lower energy crystalline form at 120 minutes and that the dissolution rate for the amorphous form at 120 minutes is significantly higher than the rate for the crystalline form at 140 minutes. The data in Tables 2 and 3 illustrates the effect on dissolution rate as norgestimate begins to re-crystallize from the higher energy amorphous form. As shown by these data, the dissolution rate of norgestimate decreases as the steroid converts to the lower energy crystalline form. The data in Table 4 show that the dissolution properties of norgestimate are not only dependent on storage conditions, but also on the mixing energetics imparted during the manufacturing process. Note that as energy is imparted over time and higher levels of amorphous norgestimate are present, the dissolution characteristics improve even when storage is unprotected under accelerated conditions.

As stated in the specification at page 13, lines 11-22, taken together the data from these studies demonstrate that when a mixture of an excipient and a steroid active ingredient is subjected to sufficient mechanical energy, the excipient and the steroid active ingredient form a less crystalline, more highly energetic composition. Furthermore, under appropriate mixing conditions, the lactose component stabilizes the steroid in a highly energetic, substantially non-crystalline state, thus preventing recrystallization of the steroid. The highly energetic, non-crystalline steroid active ingredient dissolves more readily and is better able to maintain desirable dissolution characteristics under a variety of conditions of ambient humidity and ambient temperature.

In view of the foregoing, applicants submit that the specification clearly sets forth the criticality of the non-crystalline form of the steroid hormone with respect to both the dissolution rate and stability. Accordingly, applicants believe that the claimed invention patentably distinguishes over Gast in view of Merck, since neither reference, either alone or

in combination, teaches such criticality. Accordingly, applicants request that the rejection issued under section 103 be removed.

Applicants request that a Notice of Allowance be issued in this case at the earliest possible date.

Applicants hereby petition for a three-month extension of time to respond to the Office Action of May 4, 20006. Please charge the fee required under 37 C.F.R. 1.17(a)(3), any deficiency in this fee, and any other fees that may be required to Deposit Account No. 10-0750/ORT-1548/JSK.

Should the Examiner have any questions regarding this Response, please contact the undersigned attorney at the telephone number listed

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